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Title: PRESSURE MEASUREMENT DEVICE

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REMARKS

This responds to the Office Action dated July 23, 2004.

Claims 72, 87, 92, 97, 100, and 103 are amended, and claims 117-123 are added; as a result, claims 57-64, 66-69, 72-76, 78-81, 83-85, 87, and 89-123 are now pending in this application.

Information Disclosure Statement

Applicant respectfully requests that a copy of the 1449 Form, listing all references that were submitted with the Information Disclosure Statement filed on April 14, 2004, marked as being considered and initialed by the Examiner, be returned with the next official communication.

Examiner Phone Interview Summary

Applicant thanks Examiner Robert L. Nasser for the in-person interview on September 29, 2004. (Applicant notes that the Interview Summary record incorrectly stated that the interview was telephonic.) Applicant's representative attorney Robert Atkinson and Examiner Nasser discussed additional limitations to the claims and arguments against combination of references in the §103 rejections. Examiner Nasser agreed that rejections based on Durand et al. (U.S. Patent No. 3,893,451, hereinafter "Durand") would be overcome by including a limitation that the inner layer of the catheter as recited in the rejected claims is harder than the outer layer of the catheter and filing a terminal disclaimer. Examiner Nasser indicated that further consideration would be required on Applicant's argument that if Durand's catheter is modified to be implantable, the catheter need not to be as long, thus eliminating the need for the second layer to address the resonance frequency problems associated with the relatively long catheter as taught in Durand.

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§112 Rejection of the Claims

Claims 72, 87 and 99-104 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

Claims 72 and 87

Claims 72 and 87 are amended to better describe the recited subject matter. Support for the amended is found, for example, on Page 5, line 17 of the Application. Applicant believes that the amendment has addressed the issue raised in the rejection.

Applicant respectfully requests reconsideration and allowance of claims 72 and 87.

Claims 99 and 102

Applicant respectfully traverses the rejection. Applicant submits that the subject matter recited in claims 99 and 102 is described, for example, on Page 20, lines 10-11 of the Application.

Applicant respectfully requests reconsideration and allowance of claims 99 and 102.

Claims 100 and 103

Claims 100 and 103 are amended to better describe the recited subject matter. Support for the amended is found, for example, on Page 21, line 4 of the Application. Applicant believes that the amendment has addressed the issue raised in the rejection.

Applicant respectfully requests reconsideration and allowance of claims 100 and 103.

Claims 101 and 104

Applicant respectfully traverses the rejection. Applicant submits that the subject matter recited in claims 101 and 104 is described, for example, on Page 22, lines 10 of the Application.

Applicant respectfully requests reconsideration and allowance of claims 101 and 104.

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§103 Rejection of the Claims Using Durand and Brockway

Claims 57, 59, 61-64, 66-68 and 105-110 were rejected under 35 USC § 103(a) as being unpatentable over Durand et al. (U.S. Patent No. 3,893,451) in view of Brockway et al. (U.S. Patent No. 4,846,191, hereinafter "Brockway").

Claim 57

Applicant respectfully traverses the rejection and submits that the Office Action has not set forth a proper *prima facie* case of obviousness. Pursuant to M.P.E.P. § 2143.01, the fact that references can be combined or modified does not render the resultant combination or modification obvious unless the prior art also suggests the desirability of the combination or modification. For example, in addition to the other distinctions set forth in prior communications (which are incorporated herein by reference), Applicant submits that even if Durand were combined with Brockway, the result would not include a second layer on the pressure transmission catheter as recited in claim 57. More specifically, if Durand's catheter is modified to be implantable as allegedly taught by Brockway, the resulting catheter need not to be as long, thus eliminating the need for the second layer to address the resonance frequency problems associated with the relatively long catheter as taught in Durand.

Durand teaches a pressure transmission tube having a length of 50 to 300 cm. (Durand, column 3, lines 7-11). Durand also teaches that "the resonance frequencies should be eliminated in the pressure transmission tube by resorting to a sequence of pipe sections having mutually shifted resonance frequencies" (Durand, column 2, lines 35-38). To this end, Durand suggests two embodiments for the pressure transmission tube: one with a reduced inner diameter neck portion; and one with two separate tube sections of different inner diameter connected end-to-end. (Durand, column 2, lines 39-59). As shown in Figures 2 and 3 of Durand, the neck portion 3 is provided by an external tubular insert 4 made of stainless steel, copper or aluminum. (Durand, column 3, lines 31-36). Thus, the tubular insert 4 (or the "second layer of material" as characterized by the Examiner) is provided for purposes of eliminating resonant frequencies.

By contrast, Brockway teaches an implantable pressure transmission catheter that has a length of 5 to 6 cm or 15 to 25 cm, depending on the application. (Brockway, column 6, lines 14-16). Applicant is unable to find in Brockway any teaching or suggestion of a two layer

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pressure transmission catheter, let alone a need to eliminate resonance frequencies in its relatively shorter pressure transmission catheter. Thus, it is believed that the proposed combination of references fails to suggest the desirability of using Durand's pressure transmission tube in the implantable pressure measurement device of Brockway, and is therefore not a proper basis for an obviousness rejection.

Applicant respectfully requests reconsideration and allowance of claim 57.

Claims 59, 61-63, and 105-107

Applicant respectfully traverses the rejection of claims 59, 61-63, and 105-107. Claims 59, 61-63, and 105-107 are dependent on claim 57. Thus, the discussion above for claim 57 is incorporated herein to support the patentability of claims 59, 61-63, and 105-107.

Applicant respectfully requests reconsideration and allowance of claims 59, 61-63, and 105-107.

Claim 64

Applicant respectfully traverses the rejection. For the same reason as discussed above for claim 57, Applicant submits that the Office Action has not set forth a proper prima facie case of obviousness.

Additionally, Applicant is unable to find in Durand and Brockway, among other things, a suggestion or motivation to modify the pressure transmission catheter of Durand or Brockway to include a lumen filled entirely with a pressure transmitting gel, as recited in claim 64. Indeed, Brockway appears to teach away from filling a lumen entirely with a get. For example, Brockway relates to a pressure transmission catheter having a lumen that is "filled with low viscosity liquid 29" and a "gel 30" that "provides a means of retaining fluid and is of a viscosity much higher than that of fluid 29" (Brockway, column 5, lines 25-42).

The Office Action asserts that "it would have been obvious to modify Durand et al to use this medium, as it is merely the substitution of one known medium for another." Applicant respectfully traverses this assertion as a form of Official Notice for stating that the use of a gel "is merely the substitution of one known medium for another" without support of a reference. Applicant timely traverses this assertion pursuant to M.P.E.P §2144.03 and requests a reference

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to support the assertion or an affidavit of personal knowledge by the Examiner. Clarification of the rejection based on this assertion is respectfully requested in the next official action, or withdrawal of the rejection is believed appropriate.

Applicant respectfully requests reconsideration and allowance of claim 64.

Claims 66-68, and 108-110

Applicant respectfully traverses the rejection of claims 66-68 and 108-110. Claims 66-68 and 108-110 are dependent on claim 64. Thus, the discussion above for claim 64 is incorporated herein to support the patentability of claims 66-68 and 108-110.

Applicant respectfully requests reconsideration and allowance of claims 66-68 and 108-110.

§103 Rejection of the Claims Using Durand, Brockway, and Iwata

Claims 58 and 60 were rejected under 35 USC § 103(a) as being unpatentable over Durand in view of Brockway as applied to claims 57, 59, 61-64, 66-68 and 105-110 above, further in view of Iwata et al. (U.S. Patent No. 6,019,728, hereinafter "Iwata").

Claims 58 and 60

Applicant respectfully traverses the rejection of claims 58 and 60. Claims 58 and 60 are dependent on claim 57. Thus, the discussion above for claim 57 is incorporated herein to support the patentability of claims 58 and 60.

Additionally, the Office Action asserts that "it would have been obvious to modify the above combination to use a gel, to simplify the design." Applicant respectfully traverses this assertion as a form of Official Notice for stating that the use of a gel simplifies the design without support of a reference. Applicant timely traverses this assertion pursuant to M.P.E.P §2144.03 and requests a reference to support the assertion or an affidavit of personal knowledge by the Examiner. Clarification of the rejection based on this assertion is respectfully requested in the next official action, or withdrawal of the rejection is believed appropriate.

Applicant respectfully requests reconsideration and allowance of claims 58 and 60.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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§103 Rejection of the Claims Using Durand and Pohndorf

Claims 69, 72, 99-101 and 111-113 were rejected under 35 USC § 103(a) as being unpatentable over Durand in view of Pohndorf et al. (U.S. Patent No. 5,353,800, hereinafter "Pohndorf").

Claim 69

Applicant respectfully traverses the rejection and submits that the Office Action has not set forth a proper *prima facie* case of obviousness. For example, Applicant is unable to find in Durand and Pohndorf, among other things, a suggestion or motivation to make a pressure transmission catheter that is implantable and has a multi-durometer construction, as recited in claim 57. Durand relates to a pressure transmission tube for which "the resonance frequencies should be eliminated in the pressure transmission tube by resorting to a sequence of pipe sections having mutually shifted resonance frequencies" (Durand, column 2, lines 35-38). Applicant is unable to find in Pohndorf any teaching or suggestion of a need to eliminate resonance frequencies in its pressure sensing apparatus. Thus, it is believed that the proposed combination of references fails to suggest the desirability of modifying Durand's pressure transmission tube to make it implantable as recited in claim 69, and is therefore not a proper basis for an obviousness rejection.

Applicant respectfully requests reconsideration and allowance of claim 69.

Claims 72, 99-101, and 111-113

Applicant respectfully traverses the rejection of claims 72, 99-101, and 111-113. Claims 72, 99-101, and 111-113 are dependent on claim 69. Thus, the discussion above for claim 69 is incorporated herein to support the patentability of claims 72, 99-101, and 111-113.

Applicant respectfully requests reconsideration and allowance of claims 72, 99-101, and 111-113.

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§103 Rejection of the Claims Using Durand, Pohndorf, and Brockway

Claims 73, 74 and 78-80 were rejected under 35 USC § 103(a) as being unpatentable over Durand in view of Pohndorf as applied to claims 69, 72, 99-101 and 111-113 above, and further in view of Brockway.

Claims 73, 74, and 78-80

Applicant respectfully traverses the rejection of claims 73, 74, and 78-80. Claims 73, 74, and 78-80 are dependent on claim 69. Thus, the discussion above for claim 69 is incorporated herein to support the patentability of claims 73, 74, and 78-80.

Applicant respectfully requests reconsideration and allowance of claims 73, 74, and 78-80.

§103 Rejection of the Claims Using Durand, Brockway, and Iwata

Claims 81, 83, 84, 96-98 and 114-116 were rejected under 35 USC § 103(a) as being unpatentable over Durand in view of Brockway and Iwata.

Claim 81

Applicant respectfully traverses the rejection and submits that the Office Action has not set forth a proper *prima facie* case of obviousness. For the same reason discussed above for claim 57, it is believed that the proposed combination of Durand and Brockway fails to suggest the desirability of modifying Durand's pressure transmission tube to include the implantable transducer housing recited in claim 81.

Additionally, Applicant is unable to find in Durand, Brockway, and Iwata, among other things, a suggestion or motivation to modify the pressure transmission catheter of Durand and/or Brockway to include a lumen filled entirely with a pressure transmitting gel, as recited in claim 96. Indeed, Brockway appears to teach away from filling a lumen entirely with a get. For example, Brockway relates to a pressure transmission catheter having a lumen that is "filled with low viscosity liquid 29" and a "gel 30" that "provides a means of retaining fluid and is of a viscosity much higher than that of fluid 29" (Brockway, column 5, lines 25-42).

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The Office Actions states that "Durand et al uses a saline solution as the pressure transmission medium." However, Applicant is unable to find in Durand the "saline solution." Clarification of the rejection based on this assertion is respectfully requested in the next official action, or withdrawal of this assertion is believed appropriate.

The Office Action asserts that "it would have been obvious to modify the above combination to use a gel, to simplify the design." Applicant respectfully traverses this assertion as a form of Official Notice for stating that the use of a gel simplifies the design without support of a reference. Applicant timely traverses this assertion pursuant to M.P.E.P §2144.03 and requests a reference to support the assertion or an affidavit of personal knowledge by the Examiner. Clarification of the rejection based on this assertion is respectfully requested in the next official action, or withdrawal of the rejection is believed appropriate.

Applicant respectfully requests reconsideration and allowance of claim 81.

Claims 83, 84, and 114-116

Applicant respectfully traverses the rejection of claims 83, 84, and 114-116. Claims 83, 84, and 114-116 are dependent on claim 81. Thus, the discussion above for claim 81 is incorporated herein to support the patentability of claims 83, 84, and 114-116.

Applicant respectfully requests reconsideration and allowance of claims 83, 84, and 114-116.

Claim 96

Applicant respectfully traverses the rejection submits that the Office Action has not set forth a proper *prima facie* case of obviousness. For example, Applicant is unable to find in Durand, Brockway, and Iwata, among other things, a suggestion or motivation to modify the pressure transmission catheter of Durand and/or Brockway to include a lumen filled entirely with a pressure transmitting gel, as recited in claim 96. Indeed, Brockway appears to teach away from filling a lumen entirely with a get. For example, Brockway relates to a pressure transmission catheter having a lumen that is "filled with low viscosity liquid 29" and a "gel 30" that "provides a means of retaining fluid and is of a viscosity much higher than that of fluid 29" (Brockway, column 5, lines 25-42).

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The Office Action asserts that "it would have been obvious to modify the above combination to use a gel, to simplify the design." Applicant respectfully traverses this assertion as a form of Official Notice for stating that the use of a gel simplifies the design without support of a reference. Applicant timely traverses this assertion pursuant to M.P.E.P §2144.03 and requests a reference to support the assertion or an affidavit of personal knowledge by the Examiner. Clarification of the rejection based on this assertion is respectfully requested in the next official action, or withdrawal of the rejection is believed appropriate.

Applicant respectfully requests reconsideration and allowance of claim 96.

Claims 97 and 98

Applicant respectfully traverses the rejection of claims 97 and 98. Claims 97 and 98 are dependent on claim 96. Thus, the discussion above for claim 96 is incorporated herein to support the patentability of claims 97 and 98.

Applicant respectfully requests reconsideration and allowance of claims 97 and 98.

§103 Rejection of the Claims Using Durand, Brockway, Iwata, and Pohndorf

Claims 85, 87, 89, 90 and 102-104 were rejected under 35 USC § 103(a) as being unpatentable over Durand in view of Brockway and Iwata as applied to claims 81, 83, 84, 96-98 and 114-116 above, further in view of Pohndorf.

Claims 85, 87, 89, 90, and 102-104

Applicant respectfully traverses the rejection of claims 85, 87, 89, 90, and 102-104. Claims 85, 87, 89, 90, and 102-104 are dependent on claim 81. Thus, the discussion above for claim 81 is incorporated herein to support the patentability of claims 85, 87, 89, 90, and 102-104.

Applicant respectfully requests reconsideration and allowance of claims 85, 87, 89, 90, and 102-104.

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New Claims

Claims 117-123 were added. Applicant believes that no new matter is introduced by the addition of the new claims. Support for the first layer of material being harder than the at least one additional layer of material is found, for example, on Page 6, line 12.

Applicant believes that claims 117-123 should be considered patentable based on what the Examiner agreed during the telephone interview of September 29, 2004.

Applicant respectfully requests allowance of claims 117-123.

Allowable Subject Matter

Applicant acknowledges the allowance of claims 91-95.

Claim 75 was objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 75 is dependent on claim 69, which is believed to be patentable for the reasons discussed above. Thus, it is believed that claim 75 is patentable.

Applicant respectfully requests reconsideration and allowance of claim 75.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6912 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

BRIAN P. BROCKWAY ET AL.

By their Representatives,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this day of October, 2004.

Name

Signature